K032638

SEP 11 2003

PLANAR

510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

Date Prepared:

August 1, 2003

Submitter's Information: 21 CFR 807.92(a)(1)

Ms. Susan Hamann
Planar Systems, Inc.
400 Fifth Ave.
Waltham, MA 02451-8738 USA

Trade Name, Common Name and Classification: 21 CFR 807.92(a)(2)

Trade Name:	DOME CX™ DIGITAL FLAT-PANEL DISPLAY SYSTEM™, Models C3 Color™ and C3 Gray™
Common Name:	Picture Archiving Communications System
Classification:	892.2050
Name:	System, Image Processing

Predicate Device: 21 CFR 807. 92(a)(3)

Device Classification Name	SYSTEM, IMAGE PROCESSING, RADIOLOGICAL
Regulation Number	892.2050
510(k) Number	K013922
Device Name	CORNIS 3MP MEDICAL FLAT PANEL DISPLAY SYSTEM
Applicant	BARCO NV P.O. BOX 12038 LA JOLLA, CA 92039 2038
Product Code	LLZ
Decision Date	01/28/2002

Device Description: 21 CFR 807 92(a)(4)

The DOME CX™ DIGITAL FLAT-PANEL DISPLAY SYSTEM™, Models C3 Color™ and C3 Gray™ are flat panel hi-resolution LCD monitor systems for displaying medical images. The system consists of a LCD monitor and a high-resolution graphic control board that connects to a PACS workstation for image display. The controller board is installed into the PACS workstation computer or other computer system used to display PACS medical images.

Indications for Use: 21 CFR 807 92(a)(5)

The DOME CX™ DIGITAL FLAT-PANEL DISPLAY SYSTEM™, Models C3 Color™ and C3 Gray™ are intended to be used in displaying and viewing medical images for review and analysis by trained medical practitioners.

Technological Characteristics: 21 CFR 807 92(a)(6)

The device is an image display system consisting of computer software and components. The device does not contact the patient, nor does it control any life sustaining devices. A physician or trained medical practitioner provides ample opportunity for competent human intervention to interpret images and information being displayed.

Conclusion: 21 CFR 807 92(b)(1)

The 510(k) Pre-Market Notification for the DOME CX™ DIGITAL FLAT-PANEL DISPLAY SYSTEM™, Models C3 Color™ and C3 Gray™ contain adequate information and data to enable FDA - CDRH to determine substantial equivalence to the predicate device.

The Planar Systems, Inc., DOME CX™ DIGITAL FLAT-PANEL DISPLAY SYSTEM™, Models C3 Color™ and C3 Gray™ will be manufactured by in accordance with voluntary and safety standards.

The submission contains the results of a hazard analysis and the potential hazards have been classified as Minor.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 11 2003

Planar Systems, Inc.
% Mr. Ned Devine, Jr.
Responsible Third Party Official
Entela, Inc.
3033 Madison Ave. SE
GRAND RAPIDS MI 49548

Re: K032638
Trade/Device Name: DOME CX™ Digital Flat-Panel Display System™ Models C3 Color™ and C3 Gray™
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communication system
Regulatory Class: II
Product Code: 90 LLZ
Dated: August 1, 2003
Received: August 27, 2003

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

(Indications for Use Form)

510(k) Number: K032638

Device Name:

DOME CX™ DIGITAL FLAT-PANEL DISPLAY SYSTEM™, Models C3 Color™ and C3 Gray™ from Planar Systems, Inc.

Indications for Use:

The DOME CX™ DIGITAL FLAT-PANEL DISPLAY SYSTEM™, Models C3 Color™ and C3 Gray™ are intended to be used in displaying and viewing medical images for review and analysis by trained medical practitioners.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K032638